

Editorial: Clinical audit

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Since the publication of a *First Class Service*¹ in 1998, the quality of local health services has become an important element of performance management in the NHS. Quality standards can be used to improve clinical services, and the monitoring of compliance with the standards, using clinical audit, is a requirement for all clinical teams. Clinical audit has thus become an important element of clinical governance. But what does it mean? Official publications have described it as:

systematic and critical analysis of the quality of clinical care, including the procedures used for the diagnosis, treatment and care, the associated use of resources and the resulting outcomes and quality of life for the patient.

This activity must be undertaken by all clinical staff, with the manager's support, and be truly multidisciplinary.

Audit does not exist in isolation; it needs to be an integral part of the

quality improvement programme of any organisation and teams. So a targeted audit programme must be established that addresses clinical teams' issues and that draws on local and national priorities. The audit programme should make use of all the available local information, including:

- adverse events
- claims
- complaints
- effectiveness data
- clinical indicators

National information to draw upon will include reports from the confidential enquiries, guidance from the National Institute for Clinical Excellence, nationally agreed standards and so on. While the local information will not necessarily be available at the press of a button, it is imperative that it is collected and used in the development of a meaningful audit programme.

One has to be mindful that not all agendas can successfully be progressed simultaneously, and so a system must be in place to prioritise the topics for clinical audit. A set of criteria needs to be agreed against which each topic can be judged. This could include high-volume, high-risk, high-cost, serious concerns identified by trends in adverse events or complaints, patient focus and the degree of support from the various stakeholders. This process is important because it will allow scarce resources to be targeted on the topics that are most likely to have a major impact.

Topics for future issues

- Clinical networks
- Patient participation
- International perspective on quality assurance

Please share your practical examples with us, and email them to: mlugon@compuserve.com

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The clinical audit programme must be owned by the clinical teams and therefore the organisation's overall programme needs to represent a collation of each clinical team's priorities. This may cause disquiet in organisations that would prefer to specify audit activities centrally. Nevertheless, if the organisation makes its priorities clear and passes these to the various clinical teams along with all other available information, the programme is likely to address the overall areas of concerns.

So what else is needed for successful clinical audit? The relevant structure and process must be in place to support and monitor the impact of clinical audit on the overall quality agenda. It will be necessary to ensure that lessons learnt are disseminated. Clinical information must be readily accessible to individual clinical teams. Training needs to be available for all staff so that they have the right competencies to take part in continuous quality improvement.

An audit programme needs to have an explicit project plan that covers:

- setting of standards based on evidence
- identification of the information that needs to be collected
- design of an appropriate pro forma to collect the data
- time span and lead time for data collection
- analysis of the results
- reporting phase
- agreement of the recommendations

Once a recommendation is agreed, it needs to be implemented, and this requires the identification both of an individual who will take the lead and of the appropriate timescale within which changes will be made. Making change happen is a complex process: it needs clarity about what needs to be done, why, and how it is going to be done. It also needs measures to demonstrate that the change has indeed been achieved and is sustained. This approach may appear mechanistic to some, but unless a rigorous process is used, the changes may not be implemented, let alone sustained.

This issue deals with clinical audit and related issues. The *Clinical*

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Governance Bulletin needs you! You are all learning important lessons in progressing the quality agenda; please share them with the wider NHS so that individuals and teams are not all trying to reinvent the wheel. We are looking forward to receiving your article describing your experience on any aspect of this agenda and what you have learnt in the process.

Reference

- 1 *Quality in the NHS. A First Class Service.* London: DoH, 1998

Auditing towards National Service Framework requirements of the elderly

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- Monitoring of services in relation to the standards set by the National Service Framework (NSF) for Older People may be difficult in parts of the country with a large patient population aged over 75 years.
- Flexibility may be required in the NSF's standard setting.
- Age itself may not be a sensitive indicator of vulnerability or need for special review of medication in all areas.
- Monitoring NSF standards for this patient population may be done by

groups other than primary care trusts.

Background to an audit of the elderly patient population

All practices in East Devon Primary Care Trust (PCT) recently participated in an audit concerning elderly patients prescribed four or more medications. As people get older, their use of medicines tends to increase and 36% take four or more medicines¹. Reviewing these medications and consulting with these

patients annually is a requirement of the National Service Framework (NSF) for Older People (i.e. those aged over 75 years)².

East Devon has 15% of its population aged over 75 years, while for England and Wales as a whole the proportion is only 7%, and for the rest of Devon it is 10%.

Results of the audit: standards and achievements

- Of all patients aged over 95 years who had been prescribed four or

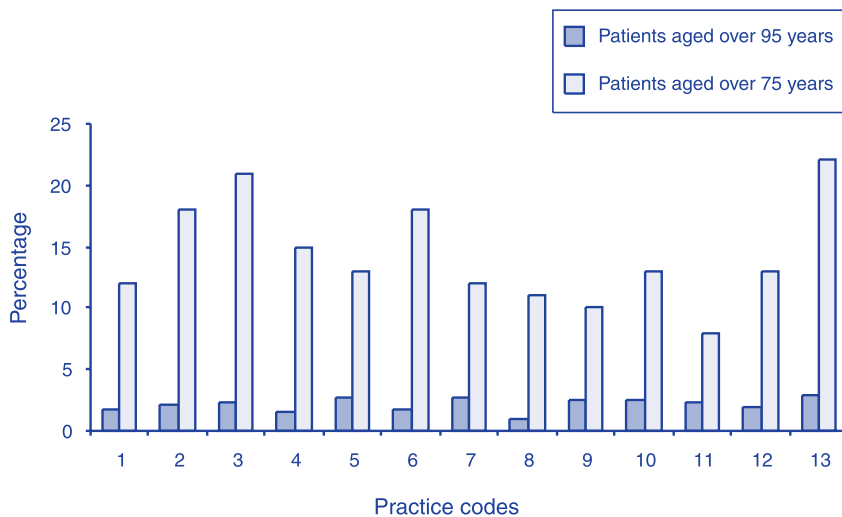


Figure 1. The proportion, by practice, of elderly patients as a percentage of the total practice population.

more medications, 137 (77%) had had a six-monthly prescription review, against the standard set by the PCT of 70%.

- Of all patients aged over 95 years who had been prescribed four or more medications, 179 (95%) had had a face-to-face consultation with the doctor over the last 12 months, against the standard set of 70%.

Lessons learnt from the audit

The process of audit revealed that systematically reviewing all patients over 75 years would be unmanageable. A decision was taken by the practice clinical governance leads group to concentrate on patients

aged over 95 years. This took the data collectors on average an hour of practice time. This was to identify the patients, determine who had been reviewed and to discover who had had an annual face-to-face consultation. One practice would have taken three hours to review all patients aged over 95 years. No estimate is made here of the time required to arrange review of those patients needing it, let alone the time required for the review itself.

Further points raised by the audit included:

- East Devon practices have large elderly populations – 22% of some practice populations are aged over 75 years (Figure 1).

- Not all practice computer systems were able to identify those patients who had four or more repeat prescriptions. The computer systems service is seeking to address this.
- Among patients identified as receiving four or more repeat prescriptions, many were receiving catheters, artificial tears and other prescriptions not really needing review.
- Age itself may not be a sensitive indicator of vulnerability or need for special review of medication and an audit of patient groups identified merely by age is extremely time consuming for East Devon practices.
- Funding to resource audits of elderly patients is not available for practices or the PCT itself.

Changes implemented

The Read code for 'Frail and elderly' (69D9) was applied so that elderly patients for review could be easily identified.

Discussion

Clinical governance leads discussed other ways of approaching the task, for example:

- concentrating on nursing homes (perhaps patients there are more at risk of iatrogenic illness because of their better adherence to medication)
- linking with pharmacists

In discussion at a clinical governance practice meeting, leads were not clear that identifying and auditing a group of patients by age and by number of prescriptions was a cost-effective process in East Devon. This may be because of better health in this part of the UK at a particular age. This may suggest that more flexibility is required in National Service Frameworks.

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Using clinical performance indicators to achieve clinical governance

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- Information provision is not an end in itself – clinical indicator ‘failures’ must be notified to and by the clinical teams, and evaluated.
- There must be full consultation at each stage of data capture to enhance ownership and to diffuse allegations of invalidity.
- Data can be confidentially reported by grouping them.
- Individual data should be notified to those concerned in a non-judgemental way.

The clinical effectiveness of some acute care interventions can be readily evaluated with the use of clinical performance indicators, which may therefore be used as a vehicle for performance improvement. In the NHS some of these indicators are already in use¹ and there is no doubt that this information, regardless of any doubts concerning its validity, can challenge attitudes and at the very least drive the provision of clinically robust and meaningful information.

In the private sector good quality clinical information is the currency of business and is routinely and comprehensively captured at the point of patient care by clinically knowledgeable staff. This information is therefore accurate enough to be used as a reliable proxy to determine the quality of clinical care.

The Quality Indicator Project

As a group (comprising six acute care hospitals) we have adopted the measures established by the Maryland Quality Indicator Project (QIP)² to help us implement and achieve clinical governance. The QIP began in 1985 as a voluntary pilot project of seven acute hospitals in Maryland, USA, that wanted to test, for data collectability and usefulness, a handful of clinical performance measures in quality improvement activities. A UK office was established to encourage and support hospitals

throughout Europe to participate in the project, which supports clinical governance and improvement in quality of care. Three different indicator sets are now available in the UK:

- acute care
- psychiatric care
- long-term care

The QIP has nearly 2000 participants worldwide. Participants collect data on any or all of the measures in an indicator set and submit these data on a quarterly basis to the UK office. Comparative feedback is then provided in the form of reports and analyses.

The indicators for which we are currently submitting data are as follows:

- unplanned readmissions within 31 days of discharge
- unexpected returns to theatre
- perioperative mortality and hospital mortality
- surgical site infections

As well as the numerator data, each indicator has a precisely defined denominator so that incidence is reported as a meaningful proportion. Hospital characteristic questionnaires are annually submitted to ensure that meaningful institutional comparisons are selected.

Unplanned readmissions

This is the only indicator for which there is an NHS near equivalent. The NHS indicator captures emergency readmissions within 28 days and the national level is in the region of 6%. The readmission rate within the private sector is in the region of 2% at 31 days. A number of issues may underlie the discrepancy, and it would be over-simplistic to attempt an analysis here.

Unexpected returns to theatre

This information is difficult to capture comprehensively in the NHS,

where information systems may be neither integrated nor capable of generating appropriate cases. In addition, in the private sector patients are more likely to return to their original hospital.

Perioperative mortality and hospital mortality

This indicator differs from the perioperative mortality described by the National Confidential Enquiry into Perioperative Deaths (NCEPOD), in that it refers to death within 48 hours of a surgical intervention rather than 28 days. This indicator may therefore highlight ‘anaesthetic’ deaths rather than ‘surgical’ ones and could also be used as an indicator of appropriate patient selection.

Hospital mortality can be used crudely to benchmark outcomes for comparison with similar institutions.

Surgical site infections

Risk-adjusted data are captured on three surgical procedures: coronary artery bypass graft, total abdominal hysterectomy and total knee replacement. Each numerator is submitted with a risk assessment category. The data are similar to those submitted to the Nosocomial National Infection Survey but the comparators that can be provided are more powerful.

Running the project

This is not just a data-gathering exercise. Information is electronically generated and individual cases are validated and evaluated by clinical teams before being categorised. Each individual case which fulfils a criterion is peer reviewed and the care processes which contributed to that outcome are examined. As well as individual case review, a simple database is kept to facilitate trend analysis over the longer term. We now give regular feedback to staff, which comprises the grouped information together with comparators.

Benefits

We feel that using this information in this fashion provides the following benefits:

- It ensures the clinical veracity of information.
- It provides an 'early warning' system.
- It provides confirmation to individual staff of the contribution

that they are making to patient care.

- It drives the upward spiral for continuous improvement.

Further developments

The next stage of using these indicators to drive quantifiable clinical improvements in processes and outcomes is now under way and

two other indicators will be developed in 2002:

- unplanned admission after day care endoscopy or other day care procedure
- unplanned transfer to the NHS

References

- 1 See www.doh.gov.uk/nhsperformanceindicators/2002
- 2 www.ncl.ac.uk/qip

Improving clinical practice

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- **Changing the clinical practice of health-care professionals requires, in the first instance, a thorough assessment of the potential barriers to that change.**
- **A multifaceted approach aimed at the needs, perceptions and requirements of the target professional group will be most effective.**
- **The change programme must be effectively coordinated and adequately resourced.**
- **Monitoring and evaluation of the behaviour change programme with feedback must take place to reinforce the message.**

The current emphasis in the NHS on evidence-based health-care and clinical guidelines aims to promote effectiveness and thereby improve quality. But this is likely to be achieved only if relevant research findings and valid guideline recommendations are appropriately incorporated into clinical practice.

Changing behaviour

The complexity of changing behaviour is well recognised and the naive assumption that when evidence is made available it is somehow accessed by health professionals, appraised and then applied in practice is now largely discredited. While knowledge of a practice guideline or a research-based recommendation may be important, it is rarely, by itself, sufficient to generate change.

A recent *Effective Health Care* bulletin¹ summarises current

knowledge and provides guidance on how best to get evidence into practice. This bulletin draws upon research carried out by the Cochrane Effective Practice and Organisation of Care (EPOC) group. The results of an overview of systematic reviews of different dissemination and implementation interventions suggested that a variety of interventions may lead to change in different settings (Box 1).

EPOC's review suggested that multifaceted interventions targeting different barriers to change are more likely to be effective than single interventions. A recent randomised controlled trial illustrates how using such an approach influenced referral for the management of menorrhagia

in primary care². The study found that an educational package with independent academics in small informal groups presenting visual, graphic and written material can positively influence GPs' prescribing of non-hormonal treatments for menorrhagia, and reduce the number of referrals.

While the approach taken by Fender *et al.*² led to successful changes in clinical practice, the same type of approach will not necessarily be successful in other circumstances and contexts. The reasons why interventions work in some circumstances but not in others are often unclear, but knowledge from relevant theory offers some explanation. Social marketing, for example, provides a

Box 1. Research findings on professional behaviour change

- Most interventions are effective under some circumstances; none is effective under all circumstances.
- Interventions based on assessment of potential barriers are more likely to be effective.
- Multifaceted interventions (involving two or more approaches) targeting different barriers to change are more likely to be effective than single interventions.
- Educational outreach is generally effective in changing prescribing behaviour in North American settings. A number of ongoing trials will provide rigorous evidence about the effectiveness of this approach in UK settings.
- Reminder systems are generally effective for a range of behaviours.
- Audit and feedback, the use of opinion leaders and other interventions had mixed effects and should be used selectively.
- Passive dissemination when used alone is unlikely to result in behaviour change. However, this approach may be useful for raising awareness of research messages.

framework for identifying factors that drive change³. Success is viewed as likely only when the needs, perceptions and requirements of the target group are determined and satisfied through the design and implementation of appropriate interventions.

The practicalities of implementing change in professional practice have been highlighted by several well known programmes, including the Framework for Appropriate Care Throughout Sheffield (FACTS)^{4,5}, Promoting Action on Clinical Effectiveness (PACE)⁶ and the North Thames research and development implementation projects⁷. Their collective experience of generating change suggests that those undertaking change need to take account of more than just research on clinical effectiveness and cost-effectiveness. A wide range of factors should also be considered, including the organisational, educational, economic and community environments of the health professional⁸.

Diagnostic analysis

The recent *Effective Health Care* bulletin suggested that these factors should be addressed using a systematic approach that also involves strategic planning¹. The first stage of this approach should involve a period of 'information and diagnostic analysis' to inform the development of an appropriate dissemination and implementation strategy. The methods used to undertake a 'diagnostic analysis' are likely to vary according to individual circumstances but they involve a combination of routine data analysis, specific surveys and interviews, and informed judgement. Such an analysis might include:

- identification of all groups involved in, affected by or influencing the proposed change(s) in practice – a wide range of people may be involved, including health professionals, managers, policy makers and the public;
- assessment of the characteristics of the proposed change that might influence its adoption;
- assessment of the preparedness of the health professionals to change and other potentially relevant internal factors within the target group;
- identification of potential external barriers to change;

- identification of enabling factors, including resources and skills.

Once completed, the results of the 'diagnostic analysis' can be used to inform the design and content of the dissemination/implementation strategy to bring about the desired changes in practice. Dissemination activities by themselves are unlikely to lead to changes in behaviour. However, this should not be taken to mean that raising awareness of the messages underpinning proposed practice changes is unimportant. While the relationship between knowledge and behaviour is rarely a linear one, awareness of 'the message' still plays an important part in changing behaviour.

Dissemination and implementation

Behaviour change is complex and, while dissemination and implementation strategies may draw upon interventions that have been evaluated in empirical research (e.g., reminders, educational outreach), other, more diffuse interventions which have yet to be evaluated may also be necessary.

Once chosen, dissemination and implementation interventions should be fully coordinated and effectively managed. They are also likely to have significant costs attached to them and will need to be adequately resourced. Additionally, the roles of various participants should be

identified and steps taken to ensure that appropriate training is provided.

Any systematic approach to changing behaviour should also include plans to monitor and evaluate the degree to which the proposed change is implemented, together with methods to maintain and reinforce any changes achieved.

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Tips for assessing how good practice spreads

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- **Communication must be targeted at raising the awareness of all key players. This is the first step in spreading good practice.**
- **The decision to proceed with a change in clinical practice is a complex process which requires the identification of those who have most influence over the relevant clinical teams.**
- **Implementation requires facilitation and close monitoring.**
- **Clear measurements need to be designed so that progress can be monitored.**

Why does one hospital ward deliver care to stroke patients according to the best available practices while a neighbouring ward has not even heard of the same techniques? Why does one primary care practice offer patients treatment for asthma that is heralded as best practice yet other practices within the same primary care group do not do the same?

One of the challenges for the NHS is to leverage the pockets of good practice and find ways to scale them up across all systems. One of the most popular paradigms for understanding how good practice spreads is that of a learning process based on social networks¹. However, it is difficult to evaluate the progress and success of work programmes aimed at spreading good practice because of the evolving and at times implicit way in which change happens. Traditional project management and reporting systems are unlikely to discover the true nature of how new ideas spread within systems, as they are traditionally based on management processes rather than on social processes. A more developmental, evolving and learning approach may be better suited to learning about and measuring the progress of spread in organisations.

The steps to innovation

A useful method of gaining insight into what is happening (or not), monitoring progress and finding ways to leverage change is to separate out three key steps in the process of the

adoption of new ideas and behaviours (see Figure 1):

- **Awareness.** Potential adopters first need to be made aware of the new ideas. What is the level of awareness on the part of the adopters? Do they know about the innovation? How much do they know?
- **Decision making.** Potential adopters will then need to decide whether or not to accept the innovation.
- **Implementation.** To what extent will the new practice be implemented?

Communication is key to the adoption process. Any programme in which the aim is for good practice to be adopted by others needs to focus on a multi-method strategy of increasing potential adopters' awareness of the benefits and details of the proposed new ideas and practices. The message and the way in which it is delivered will have an impact on the attitude a potential adopter has about the new practice and this will affect the decision-making process.

Where the adopters are relatively autonomous and can make their own decisions, implementation can happen quite quickly. In organisations where the decisions are made by a central management team, it may take much longer to achieve implementation.

The questions below can be used as part of the learning process in understanding how your local system works:

- How is information communicated?
- How is it received?
- How are decisions made based on it?
- How are new ideas eventually implemented?

Awareness

Some adopters become aware of the potential for improvement by changing their practice earlier than others. It is easy to assume that, because a memo was distributed or the item was discussed at a meeting, there is a general awareness and understanding of the problem and the good practice that could be applied to solve it. Most communication efforts are lost in the noise of the system or the depth of the in-tray; or someone just did not take any notice of the message because they did not see it as important.

Awareness is everything – it is the first step in the adoption process². Think about it – those who implement change come from the pool of people who have decided to make that change, and in turn they come from the pool of people who are aware of the need and ideas for change. You need a big pool of

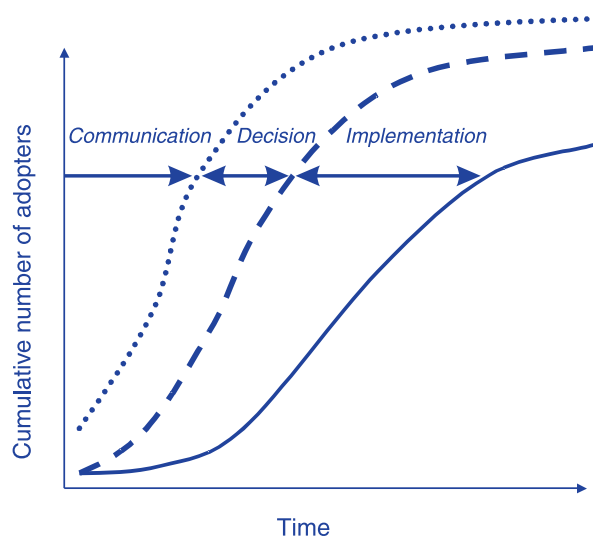


Figure 1. Phases in the adoption process.

awareness, especially if you wish to accelerate the spread of good practice.

The following questions are designed to help you think about how you might measure (or understand a bit more about) the levels of awareness in your local system.

- Against a baseline, who is now more aware than they were before the communications programme started?
- Are some groups and professions gaining awareness quicker than others? Does this matter?
- Do the opinion leaders know about the new practices? Are their views positive?
- Which of the communications methods (e.g. video, seminar, article) had the most impact in terms of raising awareness?
- Is awareness dropping off or increasing over time?
- Which part of the message or which method seems to have the least impact or create resistance to change?

Decision making

Once people are aware of the need and ideas for change, they need to make a decision as to whether they should action the change. This complex process is often made more complex where organisational permission is required. However, this is one stage in the spread and adoption process in which external support may be helpful. Project leaders, clinical leads or managers can identify the issues and then support the individuals in making their decision. You can use the following questions to help you understand more about how you can help potential adopters to decide to make a change or to identify potential barriers to progress.

- Who needs to make the decision for the new ideas and practices to be adopted?
- Who has made the decision to adopt the new ideas and to change their practice?
- What is the threshold for someone to decide to make a change? What can be done to help the adopter over this barrier?
- Has the decision been made to adopt all the new ideas, or just part of the system being spread? And why?
- What is their reason for making the decision?

Contributions

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- Complaints
- Risk management
- Effective strategy
- Knowledge management
- Effective teamwork
- Clinical errors

- 1 The audience is predominantly practising clinicians and managers, so please make your article as practical and relevant to everyday practice as possible.
- 2 Length: 500–800 words plus a maximum of five references in Vancouver (numerical) style.
- 3 Illustrations: where appropriate, use tables, charts, summary boxes etc. to present information, and to break up the text.
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- When did they make the decision?
- What or who influenced the decision making?
- What is stopping a decision being made?
- Which opinion leaders influence the target group of adopters?

Implementation

This is the most obvious area for measurement and checking progress. You may need to go through the earlier steps to discover points of leverage – small interventions that support the spread and adoption process.

- Has the new practice been implemented?
- Are the results and benefits

similar to those achieved by the pilot projects?

- Have all the parts of the new practice been implemented, or just bits of it? And why?
- Do the adopters feel they made the right decision? What are the implications of this?
- What messages are the new adopters giving to others, and in what way are they sharing their experiences?
- What influenced the implementation that was not part of the formal communication and project activities?
- To what extent was the innovation adapted by the adopters? What might this mean for future plans for spread and communication?

Conclusion

It is easy to focus on good practice and put all your efforts into trying to deliver improvements through it being spread and adopted by others. In just the same way as improvement projects need to have clear measurements to assess their progress, spread needs a similar rigour. Just measuring the implementation stage may not give you sufficient information to support the change process, especially in complex systems. By assessing the levels of awareness in your target adopter population and by gaining insight into the decision-making process, you may understand more about how you can enable the spread of good practice.

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The RSM Forum on Quality in Health Care organises and supports an annual Millennium Quality Improvement Travel Fellowship. It is intended to provide an opportunity for a person working on quality improvement in health-care in the UK, who would not normally get such an opportunity through their work, to travel either nationally or internationally to study the theory and practice of quality improvement in health-care. It is open to anyone working in health-care in the UK, and there is no requirement to be a member of any particular profession or organisation.

The closing date for applications this year is 30 November 2002. There is no application form. Applicants are asked to provide a curriculum vitae which highlights their work on or contribution to quality improvement, and a statement of up to 600 words outlining how they would propose to use the travel fellowship to further both their own personal development and their work on and contribution to quality improvement in the UK. The successful applicant will be notified in January 2003.

Once an award has been made, the recipient is asked to prepare a budget and timetable outlining in more detail how he or she plans to use the award. The budget may seek funding of up to £1500. The timetable should usually show the award being used within a six-month period.

Applications should be sent to Laura Milne, Academic Office, Royal Society of Medicine, 1 Wimpole Street, London W1G 0AG (telephone 020 7290 3942).

WhoWhatWhere?

Clinical audit on the web

Clinical Audit Association
<http://www.the-caa-ltd.demon.co.uk/>

Clinical Resource and
Audit Group
<http://www.show.scot.nhs.uk/crag/>

Using computers in clinical audit
<http://193.128.6.134/data/abcmc13.htm>

United Bristol Healthcare Trust,
clinical audit pages
<http://www.ubht.org.uk/clinicalaudit/>

Brighton & Sussex University
Hospitals, clinical audit pages
http://www.brighton-healthcare.nhs.uk/CESU/clinical_audit.htm

The Editors' Choice

National Institute for Clinical Excellence
<http://www.nice.org.uk/>

A very informative section on clinical audit contains information on principles of best practice, answers to frequently asked questions, audits in progress and completed audits.

Royal College of Surgeons of
England, 'Methodologies for clinical
audit in dentistry'
<http://www.rcseng.ac.uk/dental/fds/pdf/clinicalaudit.pdf>

University of Oxford, clinical audit
pages
<http://www.medicine.ox.ac.uk/cairns/ClinGov/clinicalaudit.htm>

King's College, London, 'Clinical
audit in four health professions'
<http://www.kcl.ac.uk/ip/gianbrown/PDFs/Capexec.pdf>

Wolverhampton Health Community,
clinical audit pages
<http://www.wolverhamptonhealth.nhs.uk/rwh/clinicalaudit/default.htm>

Primary care clinical governance: what's happening on the ground?

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- To implement clinical governance in primary care, a common understanding must be reached by all members of the health-care team.
- For clinical governance to have a positive impact it must be accepted as 'part and parcel' of the job and not an add-on.
- Lack of resources (time, administration, information technology) remain the main barriers to the implementation of clinical governance in primary care.
- In order to facilitate an emotional commitment to clinical governance, these barriers should be overcome – primary care organisations need to continue to invest time and resources into practices so that early progress is maintained.

This paper reports the results of two phases (Table 1) of a larger study in which we used focus groups, individual interviews and feedback reports to collect data from some of the key players in the development of primary care clinical governance in the south-west of England. The aims of the overall investigation were:

- to explore the development of clinical governance within primary care in the south-west
- to identify any barriers that were perceived to hinder implementation of clinical governance

- to identify the drivers that were perceived to nurture implementation

This paper reports the first wave of data collection from clinical governance leads at a practice level and members of the multidisciplinary primary care team. Data were collected between February and August 2001. A total of 24 people – GPs, practice managers, practice nurses, receptionists, a district nurse, a health visitor and a primary care manager – representing 24 different practices and 11 different primary care organisations (PCOs) – were interviewed for these phases of the study. Practices ranged in size from single-handed practices with 2400 patients to large practices with seven partners, two retained GPs and 13,000 patients. Interview transcripts were analysed using grounded theory.

Key findings of the interviews

Defining clinical governance

All except one of the 24 participants had a good basic knowledge of clinical governance although, as expected, their focus tended to be narrower than that expressed by PCO-level clinical governance leads in earlier phases of the larger study.

Participants described clinical governance in terms of three components – tools, culture and accountability (Table 2) – although

the overall process was described as a patient-focused, whole-team approach to quality improvement. Clinical governance was generally seen as facilitating the functioning and smooth running of the surgery, but there was some consensus that 'clinical governance' was a 'catch-all' phrase that 'covered a multitude of sins'. The definition offered by study participants was influenced and shaped by directives from the Department of Health and NHS Executive, by the National Service Frameworks (NSFs), by PCO clinical governance leads and by incentives offered by the PCO.

The positive impact of clinical governance

It would appear that clinical governance is becoming embedded in the day-to-day working lives of the 24 practices that participated in our study. At the practice level, clinical governance tended to be viewed as a positive concept, and appeared to slip relatively comfortably into the working week; it was described as being 'part of the norm' and 'part and parcel' of the job (Table 3). Practice leads normally considered it to be a shared multidisciplinary team activity and it was generally felt that clinical governance fitted 'very well' into the recent and ongoing changes in the NHS, including Personal Medical Services contracts and revalidation.

Among practice-level leads there was overwhelming support for the

Table 1. Phases in a study of the development of primary care clinical governance

Phase A	Phase B	Phase C	Phase D ^a	Phase E ^a	Phase F	Phase G
Focus groups with clinical governance leads of primary care organisations	Interviews with resigned clinical governance leads of primary care organisations	Interviews with members of the boards of primary care organisations	Interviews with clinical governance leads at practice level	Interviews with members of the primary care teams	Focus groups with users of primary care services	Interviews with 'national figures'

^aPhases D and E are the subject of this paper.

Table 2. How practice-level participants defined clinical governance

Tools ^a	Culture ^a	Accountability
Questioning	Quality	Monitoring
Setting targets	Openness	Measuring
Significant-event audit	Patient oriented	'Big Brother'
Conventional audit	Whole team	Performance review
Documenting	Reflective practice	Responsibility
Comparative data	Proactive	Meeting targets
<i>'formalising good practice'</i>		

^aThe categories 'Tools' and 'Culture' contained further examples and only a selection is presented here.

concept (and indeed the tasks) of clinical governance, although two of the five GP participants felt very dissatisfied with the process. Some practice leads saw clinical governance as representing a 'sea change' but the majority concurred with the view that the process was 'not that foreign to us'. Some team members felt that clinical governance was 'about doctors, nurses and accountants' and that administrative and support staff had little involvement or interest in the process. Although generally seen as a positive process, there was consensus that the 'starting point' mattered to the ease with which practices adopted clinical governance.

Tensions and challenges

Participants reported a range of difficulties with clinical governance. The main problems experienced related to pressure of time and lack of support (both administrative and in terms of information technology) for the tasks that needed to be carried out, logistical difficulties at a practice level and emotional barriers

to the process (Table 4). Several participants (both leads and team members) experienced confusion or difficulty with some of the theoretical aspects of clinical governance.

Some participants felt 'disconnected' from the large PCOs. In particular, single-handed practices felt vulnerable in relation to the comparison of their data to data generated by large practices, and felt that there was sometimes room for distortion and exposure. There was some concern expressed by both practice leads and team members that clinical governance had the potential to become 'a paper exercise', with some practices reportedly 'ticking boxes' and doing the minimum amount of work.

Conclusions

We would suggest that there is evidence that clinical governance is becoming embedded in the day-to-day lives of the 24 practices that participated in our research; indeed, the majority of our participants

expressed positive feelings about the concept and many of the tasks of clinical governance. Most practices reported 'making a start' with the NSFs, NSF-influenced auditing, significant-event auditing, dealing with complaints, collecting data, establishing comparable databases, practice learning plans, practice and professional learning plans, staff appraisals, practice away days, continuing professional development, and using evidence-based practice. However, three components of clinical governance caused particular difficulties for many of the participants:

- dealing with *slight* under-performance
- establishing GP appraisal
- developing *meaningful* patient participation

Additional difficulties at a practice level related to pressure of time, lack of resources, lack of support and to some emotional and conceptual concerns around the implementation of the framework. PCO clinical

Table 3. The positive impact of clinical governance at practice level

Standardisation	Culture	Clinical services	Resources
Systematic Standards	Better service Communication	Better-treated patients Management of chronic diseases	Support from PCO Protected time
Focused Structured	Teamwork Multidisciplinary	Preventive care More clinics	Task-specific funding Use of information technology
Data collection Consistency Checks and balances	Reflective Proactive PCO approach	Personnel and skill mix	Quality of training Evidence-based practice Bringing isolated professionals together
Measures Monitored	Prevents 'festering' 'Taking time out'		
<i>'We're not just ticking boxes; this isn't just some add-on'</i>			

Table 4. The challenges facing the implementation of clinical governance at practice level

Workload	Logistical issues	Conceptual tensions	Emotional barriers
Lack of time	Finding locums	'Levelling down'	Variable PCO support
High workload	Back-filling	Discouraging diversity ('convergence')	Feeling 'disconnected'
Reading	Reacting versus directing	Lack of grounding	'Disjointed' process
Paperwork	Lack of role clarity	Interface between primary and secondary care	Vulnerability
Lack of administrative support	Unclear accountability	Torn loyalties (between own practice and wider PCO)	Low morale
Deadlines	Lack of training (in specific areas)	Appraisals	Uncertainty/lack of clarity about level of authority
Lack of funds	Getting whole team together	Poor performance	Stressed/weary/anxious/overwhelmed
Speed of change	Engaging patients		Heightened sensitivity

'Being all things to our patients and our political masters, there is a need for realism'

governance leads need to continue to invest time and resources in practices so that early progress can be maintained.

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expressed in this paper are those of the authors and not necessarily those of the NHS Executive South West.

Further reading

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Sweeney G, Sweeney K, Greco M, Stead J. Exploring the implementation and development of clinical governance in primary care within the South West region: views from PCG clinical governance leads. Wisdom website, spring virtual conference, February 2001, <http://wisdomnet.co.uk/sweeney.htm>

Sweeney G, Sweeney K, Greco M, Stead J. Moving clinical governance forward: capturing the experiences of primary care group leads. *Clinical Governance Bulletin* 2001;2(1):6-7

Top tips for clinical audit

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- **Frameworks.** Clinical audits are most effective when they are part of a structured programme, planned and scheduled to fit with the priorities of the clinical staff, directorate or trust, and when the results can be implemented as part of overall service development. If the audit is developed and its results are reported within such a framework, everyone will be aware of the audit programme and their role in it.
- **Identifying topics for audit.** Full participation in identifying and agreeing topics for audit reduces resistance to change and increases the commitment to both undertaking the audit and making changes as a result of it. Participants should include health-care professionals, managerial staff,

- patients and carers, and others who may have a view on the area of clinical care being considered.
- **Commitment.** Commitment to the audit and the topic is crucial – a feeling of ownership will improve the quality of the audit and increase the motivation to improve practice, even before the results are able to guide changes. Audit undertaken in a culture of openness to change, where this is seen as a valid activity and a valid use of resources, will be more likely to result in successful change.
- **Keep it simple.** Clinical audits that can be clearly explained – in terms of purpose, methods and anticipated outcomes – are more likely to be accepted and acted on. Where the reason for the audit is not clear, gaining commitment to

- it may be difficult. Being able to say we are looking at X, by doing Y, so we can improve Z, quickly communicates to others why we are doing this work and what their contribution might be.
- **Documentation.** Writing down and circulating the reason for doing the audit, the evidence base for the standards, the methodology and expectations of changes, with clearly defined roles, responsibilities and timescales, supports effective audit. Defining personal responsibility and specific actions reduces the likelihood of audits failing in either process or outcome. Identifying potential barriers earlier rather than later enables them to be considered and to be accounted for in the audit plan.